IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

THE CITY OF HUNTINGTON,	:	Civil Action
Plaintiff,	:	No. 3:17-cv-01362
v.	:	
AMERISOURCEBERGEN DRUG CORPORATION, et al.,	:	
Defendants.	:	
CABELL COUNTY COMMISSION,	:	Civil Action
Plaintiff,	:	No. 3:17-cv-01665
v.	:	
AMERISOURCEBERGEN DRUG CORPORATION, et al.,	:	
Defendants.	:	

BENCH TRIAL - VOLUME 37
BEFORE THE HONORABLE DAVID A. FABER, SENIOR STATUS JUDGE
UNITED STATES DISTRICT COURT
IN CHARLESTON, WEST VIRGINIA

JULY 9, 2021

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PROCEEDINGS had before The Honorable David A. Faber, Senior Status Judge, United States District Court, Southern District of West Virginia, in Charleston, West Virginia, on July 9, 2021, at 9:00 a.m., as follows:

THE COURT: Good morning, everybody.

MS. MAINIGI: Your Honor, just to clean up the housekeeping, we've accepted -- or we would be willing to accept, if Your Honor is still willing to offer, the invitation to do closings the week of the 26th.

And, so, the plaintiffs and defendants have agreed to do the closings on the 27th and 28th if that still suits Your Honor.

We would also propose six hours per side. And defendants will probably divide up 2-2-2 for planning purposes.

THE COURT: Okay. 27 and 28?

MS. MAINIGI: Yes, Your Honor.

THE COURT: Mr. Farrell.

MR. FARRELL: Yes, sir. And, so, the plaintiffs -- I don't know that we would use the entire six hours. All we insist on is equal time available. And we would also like to reserve for rebuttal closing.

THE COURT: Okay. Well, this tells me all I need to know for now and that's what we'll do.

MS. MAINIGI: Thank you, Your Honor.

THE COURT: Now, are we ready to -- we have one witness today; is that right?

MS. WICHT: That's right, Your Honor.

THE COURT: Okay.

MS. WICHT: Good morning, Your Honor. Cardinal Health calls John MacDonald.

THE COURT: Okay, Ms. Wicht.

THE CLERK: Would you please state your name.

THE WITNESS: John J. MacDonald, III.

THE CLERK: Thank you. Please raise your right hand.

JOHN J. MACDONALD, III, DEFENDANTS' WITNESS, SWORN

THE CLERK: Thank you. Please take a seat.

THE COURT: Good morning, sir.

THE WITNESS: Good morning.

THE COURT: Whenever you're ready, Ms. Wicht.

MS. WICHT: Thank you, Your Honor.

DIRECT EXAMINATION

BY MS. WICHT:

Q. Good morning, Mr. MacDonald. Could you please start by introducing yourself to the Court?

A. Good morning. My name is John Joseph McDonald, III.

Q. And what is your current job, Mr. MacDonald?

A. I am the Principal Executive Officer and President of the Berkeley Research Group.

Q. And what is the Berkeley Research Group, or BRG as we've commonly referred to it?

A. It's a global consulting firm comprised of approximately 1,400 individuals. We have many services, but one of our dominant services is we provide expertise in legal and investigation settings.

Q. And were you one of the founding members of Berkeley Research Group?

A. I was.

Q. And could you -- are you a member of any particular practice groups or practice areas at BRG?

A. In addition to serving in an executive role with the firm, I am one of the senior leaders of our health analytics practice.

Q. And could you just briefly describe the type of work that you do at BRG in addition to your -- let's leave aside your sort of executive responsibilities with the firm. Other than that, could you describe the work you do?

A. I deal with economic, financial, and accounting issues within the healthcare space, particularly related to roles and matters involving very large datasets.

So I have a particular emphasis around data analytics. I have worked with all types of entities within the healthcare continuum, but with a special focus on the pharmaceutical supply chain.

Q. And how long have you been doing that type of work, data analytics in the healthcare space, or data analytics in general?

A. 25 plus years.

Q. And did you work at other companies prior to founding BRG and working there?

A. I have.

Q. And what are some of the other companies that you worked at?

A. I began my career with Navigant Consulting, actually at a predecessor brand name of Navigant Consulting from predominantly accounting and finance oriented individuals.

I left Navigant to join the Law and Economic Consulting Group which was a firm of Ph.D. economists.

I founded the Healthcare Practice at LECG. And then with a group of the economists from LECG and a few others, founded the Berkeley Research Group approximately 11 years ago.

Q. And how long -- you mentioned that you have 25 to 30 years of experience in sort of general data analytics work. How much of that time has been focused on the healthcare industry would you estimate?

A. Over the last 25 years, 95 percent plus.

Q. And over the course of your career, has your consulting work involved the analysis of large datasets?

A. It has always involved the analysis of large datasets. The definition of "large" has obviously evolved over time from -- there was a time when a couple of gigabytes of data was considered very large. And we've moved into a world where terabytes and approaching petabytes of data is now what we deal with.

Q. And has your healthcare data analytics work included analysis of trends and patterns in data over time?

A. Yes.

Q. And has your healthcare data analytics work involved developing approaches to identify outlier events or activities?

A. That is very often a core element of the work that I do with the healthcare data, yes.

Q. And could you explain what you mean by the term "outlier" and sort of how you do outlier identification in large datasets, just generally conceptually?

A. So the identification -- or outlier identification and evaluation I consider to be a two-step process. And this is something I have spoken on at conferences.

The first step is to employ an algorithm or a programmatic approach to identify things that may be a candidate for being tagged as unusual or outside of the norm.

And then the second step is to apply a, a more

subjective -- not subjective -- or expert oriented evaluation to put the data points into the context of the situation that surrounds them. So identify with program and then evaluate with judgment.

Q. Okay. And I think you mentioned earlier that you have done particularly a large amount of work with the pharmaceutical supply chain; is that right?

A. I have.

Q. And could you just describe generally, not identifying particular clients, but what types of companies you've worked with in the past in the healthcare -- in the pharmaceutical supply chain? Excuse me.

A. There are three main elements of the -- or types of players in the pharmaceutical supply chain.

At the one end, you have the manufacturers, suppliers. In the middle you have the suppliers or the wholesalers. And then at the other end, you have the dispensers. And that can be retail pharmacies, mail-order pharmacies, hospital pharmacies, et cetera.

And I have had substantial experience working directly with pharmaceutical clients analyzing their data under a variety of issues or needs. I've worked with the distributors. And I've worked extensively with the end dispensers.

Q. And in connection with that work that you've done in

the, in the pharmaceutical supply chain over the course of your career, have you examined large datasets of, for example, purchase and sales transactions?

A. I have.

Q. And in connection with your work in this case, were there a variety of large datasets that you analyzed?

A. There have been, yes.

Q. And could you just list off a few of those datasets that you analyzed for your work in this case?

A. There's the dataset as produced by the plaintiff, what I have referred to as the McCann dataset. The McCann dataset is an aggregated dataset that Mr. McCann has built from ARCOS data and other datasets that have been produced by the distributors. I have looked at his dataset.

I have looked at the underlying ARCOS data in its, in its native format, both the details data that has been produced in this litigation, as well as the publicly available data.

I have analyzed federal Medicaid Part D data that is available, publicly available. I have identified various coding sets.

One example would be from Elsevier which is a coding set that allows you to group types of drugs into drug families or drug categories. I've interacted with pharmaceutical prescription data.

Q. How about data that was produced by Cardinal Health? Is there Cardinal Health produced data that you analyzed in this case?

A. There has been. There have been data -- Cardinal Health distribution dataset which is the distributions from its sales system into the, the Cabell/Huntington region not only for opioid-related products, but for all distributions into the region.

I've also analyzed data related to their anti-diversion program, so the, the data identifying held orders, which of those held orders were released versus cut and reported to the DEA. I've looked at data related to their due diligence efforts.

Q. And have you -- Mr. MacDonald, have you testified previously as an expert in courts or other tribunals?

A. I have.

Q. And approximately how many times have you testified in court or another tribunal?

A. Prior to today in a, in a court or tribunal I believe I have testified three times in a court setting and one time in a, in an arbitration setting.

Q. And on each of those occasions, were you qualified to testify as an expert witness?

A. I have been, yes.

Q. And you have given -- have you given previous expert

testimony outside of court; for example, in a deposition setting?

A. I've been deposed several dozen times. I don't have a precise count.

Q. And speaking just very generally at a high level, what were the assignments that you were asked to undertake in this case to offer testimony today?

A. I was asked to look at the flagging methodologies as presented by the plaintiff experts in this case.

I've also been asked to look at the underlying data to be able to evaluate that data in the context of prescribing histories, prescribing data, quota data, so to both respond to plaintiff experts and to be able to describe the data that was being viewed by Cardinal in the normal course of business or that was available to the regulators and law enforcement in the normal course of business.

Q. Okay. And we'll get into the substance and the details of your opinion. But did your review and analysis of the datasets that you've described, based on your experience in data analytics, allow you to reach certain conclusions about Cardinal Health's distribution of medications and about certain opinions offered by some of the plaintiffs' experts?

A. It has.

Q. And when you were reaching those conclusions that we'll talk about today, did you rely on principles and methods

that are widely used in your field?

A. I have.

MS. WICHT: Your Honor, at this time I would offer Mr. MacDonald as an expert in data analytics related to the pharmaceutical supply chain.

THE COURT: Any objection?

MR. FULLER: Not to that qualification.

THE COURT: I'm sorry?

MR. FULLER: Not to that qualification, Your Honor.

THE COURT: All right. The Court finds that Mr. MacDonald is an expert in data analytics related to the pharmaceutical supply chain.

THE WITNESS: Thank you, Your Honor.

MS. WICHT: Thank you, Your Honor.

BY MS. WICHT:

Q. Okay. Mr. MacDonald, as part of your work in this case, did you review information reflecting the rate at which West Virginians were prescribed medications?

A. I have.

Q. And did you evaluate how those rates compared to national rates?

A. I have.

Q. And did you prepare a chart that reflects your analysis today?

A. I have.

Q. Okay.

MS. WICHT: Your Honor, I'd ask to publish Slide 1, please.

THE COURT: All right. You may.

BY MS. WICHT:

Q. Okay. Mr. MacDonald, just at a very high level, could you please describe what is the nature of the analysis that's reflected in this graph?

A. This graph depicts the rate at which West Virginians are prescribed pharmaceutical products relative to the national average. The data is pulled from an on-line data source. The source is the Kaiser Family Foundation which is a very large, not-for-profit research institute that publishes on a variety of healthcare-related issues.

Q. I'm sorry.

A. For example, if you look at 2005, the way to read this chart is the average West Virginian in 2005 was prescribed 15.3 pharmaceutical prescriptions. And that is 41.7 percent higher than the national average of, of prescriptions per capita.

Q. Okay. So if we look at this chart, then, Mr. MacDonald, am I correctly understanding that what's being reflected by the blue bars is the amount that West Virginians are above the national average? Is that right?

A. That is correct.

Q. And you mentioned in 2005 it was 41.7 percent above the national average. And how much above the national average was West Virginia in 2010?

A. 54 percent above the national average.

Q. And according to the data that you reviewed, how many prescriptions per capita were there in West Virginia in 2010?

A. 18.5.

Q. And let's do the same for 2015, Mr. MacDonald. How many -- what was the average prescriptions per capita for West Virginians in 2015?

A. 21.8.

Q. And was that above the national average and by how much?

A. That was above the national average by nearly 72 percent.

Q. And these figures, Mr. MacDonald, are these for all prescriptions of any kind, not just opioids, just all medications?

A. They are inclusive of opioids, but it is everything. It's heart medication. It's Lipitor. It is anything that involves a prescription.

Q. And did you conduct additional analyses comparing the levels of opioids in West Virginia as compared to national

levels?

A. I have.

Q. And did you prepare a chart reflecting that analysis as well?

A. I have.

MS. WICHT: Mr. Simmons, if we could move to Slide 2, please.

BY MS. WICHT:

Q. Okay. Turning to the next set of bars on our graph, Mr. MacDonald, first, could you just start by identifying what data you were analyzing in those blue bars?

A. This is from the distribution data as reflected in the ARCOS retail drug summaries.

Q. And, again, what is the -- what's being represented in the graph? In other words, what is, what is the blue -- what are the blue bars showing us?

A. The blue bars show that the volume of opioids distributed into Virginia [sic] on a per capita basis is 45 percent higher than the volume of opioids distributed on a per capita basis throughout the entire United States.

THE COURT: You said Virginia. I think you meant West Virginia.

THE WITNESS: I'm sorry. West Virginia. I live in Virginia.

THE COURT: We're very sensitive about that.

(Laughter)

THE WITNESS: I -- my sincere apology to all West Virginians.

MS. WICHT: Thank you, Your Honor.

BY MS. WICHT:

Q. Okay. So the blue bar reflects that West Virginia is 45.3 percent above the national average in terms of the distribution of prescription opioids; is that correct? Did I understand that correctly?

A. You did. That is correct.

Q. And does that reflect distributions to all dispensers in West Virginia?

A. It does.

Q. And did you do an analysis to, to look at the distributions made only to hospitals in West Virginia?

A. I have.

Q. Okay. And tell us the results when you look only at hospitals in West Virginia.

A. So the hospital population is a subset of the larger population. So isolating just on distributions directly to hospitals in West Virginia, they are 40.5 percent higher on average on a per capita basis compared to distributions made to hospitals on a per capita basis nationally.

Q. So is it fair to say, Mr. MacDonald, that West Virginia

is substantially higher than the national average in terms of both the volume of all prescriptions and the volume of opioids?

A. Yes. And, in fact, it's higher when you look at all prescriptions.

Q. Relative to opioids?

A. Relative to the opioids, yes. But they are above average on a per capita basis compared to the national averages.

Q. Did you also review data in the course of your work related to West Virginians' use of certain non-opioid pain medications?

A. I have.

Q. And did you prepare a table that reflects your analysis?

A. I have.

MS. WICHT: Mr. Simmons, could we please publish Slide 3?

BY MS. WICHT:

Q. Okay. Mr. MacDonald, is this the table that you prepared?

A. It is.

Q. Okay. So let's start by identifying what data you were analyzing here, please.

A. So I do not have access to a dataset or was unable to

identify and achieve access to a dataset that dealt with the entire population for non-opioid pain medication. However, there is a publicly available dataset from the federal government dealing with Medicaid beneficiaries --

Q. Medi --

A. I'm sorry, Medicare beneficiaries that, that allows one to look at the prescribing behavior across all drugs within the Medicare population.

What I have prepared here is a comparison on a per capita basis within the Medicare population within Virginia -- West Virginia and within the, the entire nation.

Q. Before we go to the results of that, let me just ask you one more question about the data. I see that the table reflects that you were looking at the years 2013 through 2016. And could you just explain why those were the years that you were analyzing here?

A. The -- those were the years that the data was available on-line at the time I published my report.

Q. Okay. And then if we look at the first line in the table, it lists a drug product that's labeled as NSAIDS. Do you understand that to refer to non-steroidal anti-inflammatory drugs?

A. I do. That's a class of pain relievers that are non-opioid related pain relievers.

Q. But they are prescription pain relievers? Is that your

understanding?
A. That is correct.
Q. Okay. And what did you conclude from the Medicare Part D prescription claims data about West Virginians' prescription rates for pain medications?
A. As reflected in the federal Medicare data, West Virginians receive 24 percent more prescriptions for NSAIDS than the national average.
Q. So West Virginians are -- in this dataset, West Virginians are above the national average with respect to receiving prescriptions for non-opioid pain relievers, NSAIDS; is that right?
A. That is correct.
Q. And are they also above the national average with respect to receiving prescriptions for opioid medications?
A. The, the Medicare population is above average in West Virginia relative to the Medicare population nationally.
Q. So according to this data, would it be fair to say that there's a generally higher prescription rate of pain medications in West Virginia, not just higher prescription rates of opioids?
A. In my opinion, that's what this chart suggests, yes.
Q. Okay.
MS. WICHT: You can take that one down, Mr. Simmons. Thank you.

BY MS. WICHT:

Q. Okay. I'm going to switch topics, Mr. MacDonald, and we're going to start talking about the flagging methodologies.

Did you review the expert reports of Dr. McCann and of Mr. Rafalski in this case?

A. I have.

Q. And have you reviewed the transcripts of the testimony that both Dr. McCann and Mr. Rafalski provided here at trial?

A. I have.

Q. And just to, to set the stage, Mr. Rafalski offered several different methodologies for potentially flagging pharmacy orders as part of a Suspicious Order Monitoring System; right?

A. My understanding and observation is he offered six separate methodologies.

Q. And then Dr. McCann sort of implemented those methodologies across his dataset. And then Mr. Rafalski came into court and testified about those results. Is that your understanding?

A. That is my understanding.

Q. Now, did Mr. Rafalski give testimony about which of the six methodologies he believed were viable?

A. He focuses on two of his methodologies as viable or

relevant in this matter.

Q. And were those referred to as Method A and Method B?

A. That is my understanding of how he referred to them, yes.

Q. Okay. And did you do, in the course of your work, some data analysis to evaluate how those methodologies operate in terms of flagging orders?

A. I have.

Q. Okay. I'm going to start with Method A which Mr. Rafalski also called the six-month trailing method.

Now, I know the Court has just heard about this yesterday, so just -- could you just very briefly describe your understanding of how Method A worked?

A. Method A looks at sequences of numbers in groups of seven. And if the seventh number is higher than any of the prior six numbers, it is flagged.

And, so, you look at the seventh transaction, decide whether it should be flagged or not. The algorithm makes a determination. It then moves to the eighth transaction. And based on transactions two through six, if number eight is higher than two through six, it automatically flags that transaction.

Q. And under Method A, once a -- and the transactions that, that Dr. McCann and Mr. Rafalski were looking at in this case were, were shipments, correct, shipments of opioid

medications?

A. They were aggregated shipments on a month-by-month basis.

Q. And then under Method A, once a shipment is flagged, what happens to orders after that?

A. Every subsequent shipment is automatically flagged.

Q. Now, do you believe in your opinion, Mr. MacDonald, that Method A, the six-month trailing method, is a reliable method to identify orders that are outliers?

A. Absolutely not.

Q. And why not?

A. Because it is indiscriminate in its flagging behavior. I -- regardless of the type of sequence of numbers you throw at it, it, it flags a reasonably similar number of transactions.

You can throw weather temperature data at it and it flags a high percentage of the temperature data as, as suspect or just flags. It doesn't make a determination. It just says "flagged."

You can throw random numbers like dice rolls at it and it flags them. You can throw opioid prescription order data and it flags them.

Q. As part of your testing of the reliability of Method A, did you analyze how Method A would apply to distributions of non-controlled substances by Cardinal Health in Cabell and

Huntington?

A. I have.

Q. And did you prepare a table that reflects that analysis in your results?

A. I have.

MS. WICHT: I'll ask to publish, please, Mr. Simmons, Slide 4.

BY MS. WICHT:

Q. Okay. Mr. MacDonald, let's start by -- could you just please tell us first what the items above the black line across the table represent, the hydrocodone and the oxycodone numbers here?

A. Focused on the data points in the time frame from 2006 to 2018 within the McCann dataset, that is the percentage of total hydrocodone and oxycodone orders within the Cardinal Health order system that are flagged by the McCann slash Rafalski process.

Q. And I see -- just as a slight detour, I see this is pulled from your report and I see it's referred to here as Method 1.

So just to clarify, Mr. Rafalski had, had lettered his methods, right, Method A, B, C, D, et cetera, but that Dr. McCann referred to them by numbers?

A. He had. So Rafalski Method A is equivalent to -- it is the same thing as McCann Method 1.

Q. Okay. So these numbers, 84.1 percent and 93.3 percent, are the orders that were flagged by Dr. McCann and Mr. Rafalski for hydrocodone and oxycodone respectively in this time period; correct?

A. In the time period 2006 through 2018, that is correct.

Q. Okay. And could you please generally describe the analysis that, that you did here below the black line in your table?

A. Well, to test the ability of this flagging methodology to identify true outlier events, I have created a, a sequence of monthly orders from Cardinal Health into the Track 2 pharmacies related to five commonly prescribed non-controlled substance related pharmaceutical products.

Q. And, so, this is from -- just to be clear, this was applied to the actual Cardinal Health distribution data; correct? These were not hypothetical numbers; this is actually what Cardinal Health shipped?

A. It's taking the equivalent data to what's, what's being run through for oxycodone and hydrocodone -- when I say equivalent, it's from -- the original source is the Cardinal distribution data. And I have just run it through in the identical fashion as to how Mr. McCann technically executes the model.

Q. Okay. And, so, when you applied Mr. Rafalski's Method A to thyroid medication, for example, that was shipped by

Cardinal Health into pharmacies in Cabell and Huntington, what percentage of dosage units did Method A flag of all thyroid medication shipments?

A. 92.4 percent.

Q. And when you looked at -- you looked at a few different types of high blood pressure medication. And when you applied Mr. Rafalski's Method A to Cardinal Health's shipment of high blood pressure medication into pharmacies in Cabell and Huntington, what were the results? What percentage were flagged?

A. Well, there were two, two specific high blood pressure medicines we looked at. And the range, the range of flagging was between 92.1 and 93.6 percent.

Q. And how about Metformin which is an anti-diabetic medication? When you applied Method A to Cardinal Health's shipments of that anti-diabetic medication into Cabell and Huntington, what percentage of orders did it flag?

A. 93.3 percent.

Q. So is it fair to say that when you applied Mr. Rafalski's Method A to non-controlled substances, it also -- similar to what it had been with oxycodone and hydrocodone, it ended up flagging over 90 percent of the orders?

A. Demonstrating that as a flagging mechanism, this mechanism is indiscriminate. It just flags.

Q. And I think you mentioned earlier that you had tested

it on some other things in addition to non-controlled substances. Could you just tell us a little bit about that?

A. I designed a -- a simulated a series of several hundred thousand dice rolls. And it just automatically flags dice rolls despite the fact that they're perfectly random, one through six, and it flags at roughly the same rate.

I threw a series of temperatures at it and it flags perfectly normal temperatures. And it just flags.

This is a methodology that will flag any normal distribution of numbers and, again, proving its failure to flag outlier events. If you throw a series of dice rolls where you have a six-sided dice with a six on each side, it will never flag that series of numbers, despite the fact that that is truly an outlier event. It wouldn't flag that, but it will flag a normal rolling of dice.

So it just flags normal and expected sequences of numbers. And that's a phenomenon that Mr. McCann acknowledges in his deposition to this, to this case.

Q. In your opinion, is Rafalski Method A or McCann Method 1, whichever way we want to refer to it, a reliable way to identify pharmacy orders that are outliers?

A. Absolutely not.

Q. And you mentioned in the beginning of your testimony that, that outlier identification is a two-step process. And, and where is it in that process that this methodology

is failing in your opinion?

A. It completely fails to take into the context the size of the pharmacy, the nature of the pharmacy, is it a pharmacy that's linked to a hospital. It failed to take into account whether the pharmacy has a growing market share in its region or a declining market share. It applies literally no context to what's going on in the environment around, around the pharmacy customer and the orders.

Q. And would you consider that, Mr. MacDonald, to be sort of the second step of what you described as outlier analysis where you have to look at the, the context and make a judgment?

A. Those would be the initial steps of a contextual analysis. There can be a lot of factors that would explain something that is flagged by an algorithm but is really, in fact, normal and expected.

So you have to apply a contextual analysis to, to the process of flagging unusual orders, which is a process that's directly referred to by the DEA when they say that a pharmaceutical distributor is in a position to know its customers.

Q. And would you say that Rafalski Method A, even as to that first step, sort of applying an algorithm and identifying potential outliers, does the methodology fail even on that step as well?

A. It's, it's indiscriminate. It does not identify outliers. There are mechanisms and other scenarios that you can say, the things you identify outliers. These algorithms do not identify outliers. They just flag in a predictable fashion a high percentage of whatever transaction set or dataset you feed through the algorithm machine.

Q. Let's turn to discuss Method B which Mr. Rafalski called the six-month trailing fixed first triggered method. And, again, recognizing that the Court has heard a little bit about this just yesterday, could you just please briefly describe how you understand Method B to operate?

A. Very similar to Method A. It, it's based on looking at sequences, seven numbers at a time looking at the seventh number and the prior six.

However, unlike the first method that it does that in a continuous basis and then has a carry-forward methodology, this one continues to evaluate every, every order.

But once it's triggered the first time, it establishes a threshold for that drug to that pharmacy, and every order that exceeds that threshold in the future.

So this artificial threshold that's created by the initial trigger is just assumed by the algorithm to somehow be relevant to every transaction into the future regardless of how far into the future the data series goes.

Q. And in your opinion, Mr. MacDonald, do you believe that

Method B, the six-month trailing fixed first triggered method, is a reliable method to identify orders that are outliers?

A. Again, I believe it is indiscriminate and it is incapable of identifying outliers.

Q. And as you did for Method A, did you conduct certain tests of the reliability of Mr. Rafalski's Method B?

A. I have.

Q. And as you did for Method A, did you test how Method B would apply to Cardinal Health's distributions of non-controlled substances in Cabell and Huntington?

A. I have.

Q. And did you prepare a table that reflects your results?

A. I did.

MS. WICHT: Mr. Simmons, I'd ask you to publish Slide 5, please.

BY MS. WICHT:

Q. And is this the result of that analysis, Mr. MacDonald?

A. It is, looking at the same five non-controlled substance products in the prior chart.

Q. Okay. So, again, starting above the black line where we're looking at hydrocodone and oxycodone, could you just please describe what's reflected in the chart there?

A. During the period 2006 to 2018, Mr. McCann's algorithm

that was directed by, my understanding, by, by Mr. Rafalski flagged 40.5 percent of the hydrocodone orders.

Q. And those are Cardinal Health orders, orders to Cardinal Health; correct?

A. Orders from Cardinal Health to the Track 2 pharmacy customers.

Q. Okay. And with respect to oxycodone, Method B in this time period would flag 66 percent of Cardinal Health's distributions to Cabell and Huntington; correct?

A. That is correct.

Q. And then tell us about what you did here below the black line in the table.

A. Similar to the prior chart, I ran the Cardinal Health orders for five non-controlled substance prescription drug products that were distributed to Track 2 pharmacies by Cardinal Health during this period and determined what percentage of those orders would have been flagged by the Method B, Rafalski Method B.

Q. So when you looked at, again, at thyroid medications, Mr. MacDonald, what percentage of Cardinal Health shipments to Cabell and Huntington pharmacies of thyroid medication would be flagged by Mr. Rafalski's Method B?

A. 56.8 percent.

Q. And you looked again at the two different classes of high blood pressure drugs into Cabell/Huntington. And what

percentage of those shipments would be flagged by Mr. Rafalski's Method B?

A. 62.4 percent and 71 percent.

Q. And the anti-diabetic medication, Metformin, what percentage of Cardinal Health shipments of those drugs into Cabell/Huntington would be flagged by the application of Mr. Rafalski's Method B?

A. 75.5 percent.

Q. Now, I skipped one that I want to come back to, a diuretic drug called -- I think it's pronounced Furosemide, but I'm not certain about that. We'll call it a diuretic. And what percentage of shipments of those drugs into Cabell/Huntington would be flagged by Mr. Rafalski's Method B?

A. 25.8 percent.

Q. And I notice that one is a good bit lower than the other ones. And did you analyze why that was the case, Mr. MacDonald?

A. Method B is particularly indiscriminate in flagging any series of numbers that has a growth trend embedded in it, and not flagging or flagging at a lesser rate any series of numbers that has a declining trend in the data. And that has to do with how it sets the, the threshold based on an early occurrence in the data series.

Q. So is it fair to say that the application of Method B

to non-controlled substance shipments by Cardinal Health would flag a very large percentage of those orders just as it flagged a large percentage of oxycodone and hydrocodone orders?

A. Yes.

Q. And if the prescribing of a particular medication, any medication, is growing over time, what impact does that have with respect to how Method B will apply to it?

A. It accelerates or increases the percentage of, of orders in this case that would be flagged. It is particularly indiscriminate in identifying or flagging data points in a growing series.

Q. And did you review data and information in this case, Mr. MacDonald, that indicated that prescriptions for opioids were, in fact, growing over the time period of this analysis?

A. I think that the record is clear and what was available in the publicly available DEA numbers made it clear that the prescribing experience for opioids was increasing during this period.

That number is reflected in the APQ numbers. It's reflected in the publicly available summary level ARCOS data. It's, it's not surprising. It's what was observable.

Q. And what conclusions -- well, let me just -- in your opinion, Mr. MacDonald, is Rafalski Method B a reliable way

to identify pharmacy orders that are outliers?

A. Absolutely not.

Q. And, again, sort of in your, your two-step process for outlier analysis, where is this method failing in your opinion?

A. Well, it fails on the first step because it is indiscriminate. It does not identify outlier events. It just flags. It's particularly flawed in the second step. There is no contextual analysis applied in this methodology.

Q. Okay. I want to turn -- I want to talk about the time period of the data that you reviewed, Mr. MacDonald.

When you were analyzing Cardinal Health's distribution data that was produced in this case, what was the date range for which you had that data?

A. 1996 through 2018 I believe.

Q. And as you reviewed Dr. McCann and Mr. Rafalski's flagging analysis, did you come to understand that Cardinal Health happened to possess and, therefore, had produced data for a longer time period than the other defendants?

A. I did make that note, yes.

Q. And what was the impact of having those additional years of Cardinal Health data on the results of the flagging analysis that was done by Mr. Rafalski and Dr. McCann?

A. It caused more of Cardinal's transactions to be flagged than would have been flagged had they produced data from

similar time periods to the other defendants.

Q. So more Cardinal Health orders -- a larger number of Cardinal Health orders were flagged by Dr. McCann and Mr. Rafalski just because Cardinal Health had data covering a longer time period?

A. And as Mr. McCann notes, that the longer the time period, the more likely that a series will be flagged. So he acknowledges that the length of data increases the likelihood. So a long-term predictable customer will get flagged more readily than a, a shorter-term customer.

Q. And have you prepared a sample chart that tests and demonstrates the impact on the Method B flagging analysis caused by the time period of the Cardinal data?

A. I have.

MS. WICHT: And, Mr. Simmons, I'll ask you to put up Slide 6, please.

BY MS. WICHT:

Q. And does this reflect your analysis on that question, Mr. MacDonald?

A. It does.

Q. Okay. Could you please describe for us what is reflected -- we have two side-by-side -- I don't know what you call these kind of charts. Scatter dot charts? What do you call them?

A. Scatter graphs.

Q. Scatter graphs, okay. Could you describe what's reflected in the one on the left?

A. This -- you can see that it's -- both charts have the same data points. The dots are on there, but the colors of the dots change.

So as analyzed by Mr. McCann, the left -- on the left-hand side he applies the entire dataset, including the Cardinal data produced prior to the ARCOS data.

And it demonstrates that -- you can see there if you squint your eyes, Your Honor, the blue dots on the far left represent orders that were not flagged by the Cardinal Method B -- I'm sorry -- by the McCann Method 2 or the Rafalski Method B. The --

Q. So are the -- I'm sorry.

A. I was going to say the orange dots are all of the orders that are flagged.

Q. Okay. So each dot, then, reflects an aggregate month of orders; is that right?

A. That is correct.

Q. Okay. And as Dr. McCann and Mr. Rafalski ran the analysis across the entire time period of the data that Cardinal Health produced, these dots on the left reflect the results of that flagging analysis; is that right?

A. That is correct.

Q. And we see some blue dots that are not flagged under

the line, and we see a large number of orange dots that are flagged above the line; right?

A. That is correct.

Q. Okay. And tell me what you did in the chart that's on the right here.

A. So I re-ran this series of numbers through the McCann model. I -- my report refers to it as the McCann model, but Rafalski/McCann model. But blinding the machine from data prior to 2006, so as if the only data that had been produced was the 2006 forward data.

And you can see that the number of non-flagged transactions goes through the roof. The blue dots again are flagged -- monthly orders that would not have been flagged. And you have a small number of orders that would have been flagged at the -- in the 2006 time frame.

Q. So is the only change that you made in the analysis here just changing the, the start date of the application of the methodology?

A. That's the only thing I changed.

Q. And with the -- when you started in 1996, started the flagging analysis in 1996, what percentage of the months of orders are flagged under Rafalski Method B?

A. 88 percent --

Q. And --

A. -- for this sample pharmacy.

Q. For this sample pharmacy, yes. And if you do nothing but change the start date of the analysis, what percentage of orders for this particular sample pharmacy would be flagged if you started the analysis in 2006?

A. Less than 4 percent.

Q. So did your analysis show, Mr. MacDonald, that the time period of the data considered has a large impact on the percentage of orders that are flagged under Rafalski Method B?

A. It does.

Q. And then when Mr. Rafalski reported the number of dosage units that were in orders he flagged, was that figure for Cardinal Health also substantially inflated because of the longer time period of Cardinal Health data considered?

A. It was under all methodologies, but particularly under the Rafalski Method B methodology. It's substantially overstated.

Q. And that's, that's a good clarification. I was actually going to go back to that as well. We're, we're doing Methodology B. But does this also have an impact on how Methodology A applies to Cardinal Health orders?

A. Not as large of an impact, but it does have an impact, yes.

Q. You, you talked for a moment about the impact of -- if there's a growing trend for prescriptions of a drug, how

that will impact the flagging methodologies. Let me just ask you one other thing.

Leaving aside prescriptions, if a pharmacy, a particular pharmacy is growing in its business, it's serving more customers or it's filling more prescriptions overall, how will that growth trend affect the results of the flagging methodologies, A and B?

A. Because the flagging methodologies don't take the context into account at all, a growing trend, whether that growing trend is related to the overall market or related to a particular pharmacy or related to a distributor's market share with that particular pharmacy, a growing trend will get flagged more often automatically.

Q. Okay. Our last topic this morning, Mr. MacDonald. Did Dr. McCann and Mr. Rafalski -- well, you understand that Dr. McCann and Mr. Rafalski analyzed Cardinal Health's shipments of opioid medications to pharmacies in Cabell and Huntington; right?

A. I, I do understand that, yes.

Q. And I think you mentioned this already, but did Cardinal Health produce shipment data about non-opioid medications into pharmacies in Cabell and Huntington?

A. Cardinal Health has produced its, its distribution data to its customers in Cabell/Huntington.

Q. And did Dr. McCann analyze that data from what you

could see?

A. The non-controlled substance data?

Q. Yes, sir.

A. There's no indication that he has addressed it at all.

Q. And did you see an indication that Mr. Rafalski analyzed that data?

A. None whatsoever.

Q. So, for example, if a pharmacy received a large volume of orders for prescription opioids, did Dr. McCann or Mr. Rafalski's analyses reflect whether that pharmacy also received a large volume of other medications like blood pressure medication or cholesterol or anti-diabetic medication?

A. This is a good example of contextual analysis that is completely ignored by Mr. Rafalski and Mr. McCann.

Q. Did you -- in your work in this case, did you analyze Cardinal Health's shipments of non-controlled medications into Cabell County and Huntington?

A. I have.

Q. And why did you do that analysis, Mr. MacDonald?

A. For a few reasons. First, I know that it has been indicated by the DEA and representatives of the DEA that it is a relevant measure and a factor that does put controlled substance orders into context.

Mr. Wright in his deposition in the Track 1 litigation

testified that a controlled substance ratio of 20 percent controlled substances, 80 percent non-controlled substances is normal, does not indicate anything untoward. And, in fact, there are instances where controlled substance ratios higher than 20/80 are appropriate and normal.

Q. And the higher than 20 percent could be based on other contextual analysis factors; is that, is that correct?

A. Correct.

Q. So what analysis did you conduct of the non-controlled substance data produced by Cardinal Health related to Cabell and Huntington customers?

A. I looked at, on an aggregated basis, the percentage of controlled substances to non-controlled substances distributed by Cardinal to the Track 2 pharmacies. And for the controlled substances, I broke them down between opioids and non-opioids.

Q. And did you prepare a graphic that represents the results of that analysis?

A. I have.

MS. WICHT: Mr. Simmons, I'll ask you to publish Slide 7, please.

BY MS. WICHT:

Q. And, Mr. MacDonald, could you please describe the results of your analysis as reflected in this chart?

A. Again, this is Cardinal Health distributions to its

retail pharmacy customers in the Cabell/Huntington region during the period 2006 through 2018. It's all, all volume.

And it demonstrates that 85 percent of the distributions were for non-controlled substances. 7 percent, just over 7 percent were for opioid-related products. And 7.9 percent were for non-opioid related controlled substances.

Q. So there's, there's probably been a little too much math in this case for my liking, but I think this is an easy one. Does this mean that based on your analysis of the data, approximately 92.9 percent of the medications Cardinal Health shipped to retail pharmacies in Cabell and Huntington were not opioids?

A. You've done your math correct, Ms. Wicht.

Q. Okay. Thank you. So what conclusion do you draw from this analysis, Mr. MacDonald?

A. That at the aggregate level, there's no indication that the distributions by Cardinal Health to its retail pharmacies during this time period were outside of the norm.

Q. And why did you consider them in aggregate in that way? Why did you consider all the pharmacies together? Just describe what the, what the impact of that was.

A. Well, I was looking at -- put in relation to Cardinal Health's ability to put this into the context, the overall trends of distributions into, into this particular region

based on data it had in its purview.

MS. WICHT: May I take a moment, Your Honor?

THE COURT: Yes.

(Pause)

MS. WICHT: That's all I have. Thank you very much, Mr. MacDonald.

THE COURT: Mr. MacDonald, what's your educational background?

THE WITNESS: I'm an accounting major from Georgetown University.

THE COURT: You may cross-examine.

MR. FULLER: Judge, it's going to be me. And if you don't mind -- and I know it's early for a break, but I told Ms. Wicht I wouldn't be longer than her, so we're probably about halfway. Do you mind if we take a ten-minute break?

THE COURT: No. We'll be in recess for 10 minutes.

You can step down.

THE WITNESS: Thank you, Your Honor.

(Recess taken at 9:55 a.m.)

THE COURT: Please resume the witness stand, Mr. MacDonald.

THE WITNESS: Thank you.

THE COURT: All right, sir.

MR. FULLER: May it please the Court. Mike Fuller on behalf of the plaintiffs.

CROSS EXAMINATION

BY MR. FULLER:

Q. Mr. MacDonald, we met earlier this morning, correct?

A. I met you in the lobby, correct.

Q. And I think this is the first time either of us at least recollect meeting each other, right?

A. That is correct.

Q. All right. So, I wanted to chat with you a little bit about the work you've done in this case and what you've reviewed and what you haven't reviewed; is that fair?

A. That's fair.

Q. Okay. So, you have looked at Mr. McCann's report, or Dr. McCann's report, Mr. Rafalski's report, as well as their sworn testimony, correct?

A. I have.

Q. And attached to your report is an attachment number 2 which provides your reliance materials, correct?

A. As I recall, that's the -- I don't remember if that's number 2, but my report has a chart of the materials I have relied upon.

Q. And you testified earlier some of the datasets that you looked at, some provided by Cardinal, some that you sourced yourself, right?

A. That is correct.

Q. Now, you also mentioned due diligence, that you reviewed some sets of due diligence; is that correct?

A. That is correct.

Q. Now, let me --

MR. FULLER: And I'm going to give defense counsel a copy of -- if we can pull up Plaintiffs' Demonstrative Slide number 1.

And, Judge, I actually have a P, number, too, Plaintiff's Exhibit 23656. This is the defendants' discovery responses in this matter.

May I approach the witness, Judge?

THE COURT: Yes, you may.

BY MR. FULLER:

Q. If you'll go to -- and so you know, Mr. MacDonald, the P number on the front is paginated, as well, and if you'll go to Page 9.

MS. WICHT: I'm sorry. Did you say Page 9, Mr. Fuller?

MR. FULLER: Yes.

MS. WICHT: Thank you.

MR. FULLER: And I'm going to have her put up Demonstrative number 1, which actually is a demonstrative of the answer to interrogatory or combined discovery request number 4.

BY MR. FULLER:

Q. All right. Do you have that in front of you, Mr. MacDonald?

A. I can -- I have it in my hand and on the screen, yes.

Q. All right. So, supplemental response to request number 4. Cardinal identifies their centralized due diligence. Do you have an understanding of what's meant by centralized due diligence?

A. I could hazard a guess, but I don't have an explicit --

Q. Perfect. So, let's walk through it.

A. Okay.

Q. So, when you talked earlier, you said there was a two-step process to these analyses that you did, correct?

A. Correct.

Q. There is an ID with a program or some sort of automated system, right?

A. That was my testimony, yes. That's my approach.

Q. We've talked about it in this litigation as sort of a triggering mechanism or like a methodology that Mr. Rafalski provided to Dr. McCann. Does that make sense?

A. The triggering methodology in this case is indiscriminate, but I understand what you're saying, yes.

Q. Okay. And then the second part is I think you said evaluate with judgment; is that correct?

A. To provide -- to evaluate -- I didn't use those words,

but I -- but to bring the context, to evaluate the scenario and situation around the data you're looking at.

Q. Right. You said you've got to look at contextual factors?

A. Correct.

Q. Okay. Well, what Cardinal has done is they have identified due diligence, which does -- the basis of it is contextual factors, other factors that may be considered when looking at a suspicious order or a potentially suspicious order. Because you testified that you reviewed due diligence, let me ask you, when you say due diligence, what do you mean?

A. I -- the due diligence that has been produced in this case. So, the due diligence that was available and had been maintained in the matter and has been produced in the case, I reviewed the due diligence as produced. So, I looked at the site visits, the record of held orders. That's what I was referring to.

Q. Okay. So, let's read this discovery response. Cardinal Health incorporates by reference its objections and response to this request as stated above. Subject to and without waiving its objections, Cardinal Health responds that it has produced centralized due diligence files for its customers in Track 2 at the following production numbers. Did I read that right?

A. You read that correctly.

Q. Okay. And then it provides a whole bunch of Bates numbers. Do you see that in the document?

A. I do.

Q. As well as DEA numbers, correct?

A. I do.

Q. So, Cardinal has told us that these are their centralized due diligence files for the CT2 customers. Do you know how many pages of these documents you actually reviewed?

MS. WICHT: I'll object, Your Honor, just on the basis that I think the witness testified that he -- he obviously didn't write this document and when it said centralized due diligence files, I think he testified that he wasn't sure what that meant in this particular context of this legal document.

THE COURT: Well, he testified as to what he did review to prepare his opinions and this is cross. I'll let you pursue it, Mr. Fuller. I'm not sure where --

MR. FULLER: Sure. And -- and --

THE COURT: -- you're going, but I will let you pursue it.

MR. FULLER: Thank you, Your Honor.

BY MR. FULLER:

Q. Let me make sure we're clear. You've testified already

that you reviewed due diligence produced in this case, right?

A. I have reviewed due diligence produced in this case.

Q. Okay. This is the specific due diligence that Cardinal identified when ordered to by the Court. Are you aware that there's only three pages from this spreadsheet actually in your reliance materials?

A. I have not cross-referenced this sheet to my reliance materials, so I don't know that.

Q. And the reliance materials that you identified as an attachment to your report are all the documents you were provided and that you're relying on for all of your opinions, correct?

A. They are the -- designated as the documents I relied upon for producing my report.

Q. And that you're relying on for your opinions, correct, Mr. MacDonald?

A. Those are the documents I'm relying upon for the opinions that are detailed in my report and that is what I am testifying to, what is in my report.

Q. Okay. And sitting here today, without going through your attachment number 2 to your report, you're not sure whether any of these documents are listed; is that fair?

A. I have not cross-referenced this list to the list in my report. I have reviewed substantial numbers of due

diligence events. I did not endeavor to review every single one. I was not trying to audit the historical due diligence. I was pointing out that due diligence did take place and that due diligence is completely ignored by plaintiff experts.

Q. Well, what type of due diligence did you review? Let me ask you that.

A. I reviewed the record of orders being actually flagged and evaluated and either cut and reported to the DEA or cleared and shipped. I reviewed on a sample basis the form and existence of site visits where a representative of Cardinal Health visited particular pharmacies. I reviewed the number of times site visits took place to various pharmacies as reported in the dataset.

Q. Fair enough.

MR. FULLER: So, let's now go to Plaintiffs' Demonstrative Slide 3, Gina.

BY MR. FULLER:

Q. Let's talk about the SOMS system. Are you aware of the components that comprise a Suspicious Order Monitoring System?

A. When you refer to the components, as designated by the DEA?

Q. No. How about like Cardinal? That's who you're testifying on behalf of, right?

A. I am aware of the Cardinal Health SOMS system. I did not -- I was not retained to evaluate its system or to comment on its overall effectiveness. I have observed that this system existed and for the period in which data has been produced. I have confirmed that they executed their system as described, which is contrary to observations made by Mr. Rafalski.

Q. All right. So, let's pick that apart. You're not here to testify as to the adequacy of their system, correct?

A. That is not what I was retained to do and it's not an opinion covered in my report.

Q. So, you're not providing any opinions in that regard, right?

A. I am providing an opinion that I observed that they did have a system and I have confirmed that their system, in terms of paying attention to the thresholds that they did set, that they operated based on those thresholds. I am not offering an opinion as to thresholds themselves, but the execution of the Cardinal system, Cardinal system, I am offering opinion that they did execute it as designed.

Q. Okay. Do you know when they started using a threshold system?

A. It is covered in my report. I don't have all of -- their system has evolved over time. As I recall, the system began in 2008 and what's available in the data as produced

is from 2013 forward.

Q. Okay. So, what about prior to 2008, did they have a system?

A. I was -- my understanding is that they did have a system. I've seen indications of it. I was not explicitly retained to review that system or comment on the evolution of Cardinal's strategic order monitoring system over time.

Q. Fair enough. This, I will represent to you, is from Cardinal's own documents and it was a PowerPoint that was created in 2008 that sort of lays out a SOMS system, okay?

A. Okay.

Q. And it starts with describing -- it starts with describing the order coming in. Do you see that?

A. I do.

MR. WICHT: I'm sorry to interrupt. Mr. Fuller, if this comes from a Cardinal Health document, could we please be directed to that?

MR. FULLER: Yes. It is Michael Mone's PowerPoint -- (unintelligible)

COURT REPORTER: I'm sorry. I couldn't hear that.

MR. WICHT: Yeah. Perhaps with an exhibit number or ideally a copy.

MR. FULLER: Well, I'm just using this as a demonstrative, but if I can get you a P number, I will.

I will get you that P number in a moment, but I'm just

using this as a demonstrative.

BY MR. FULLER:

Q. So, the order comes in. As you discussed earlier, there was a threshold system in place, right?

A. Yes.

Q. And that threshold system is that mechanical system that would identify and potentially block an order, right?

A. Flag or block an order, yes.

Q. Okay. Do you know what the next step in the process is according to Cardinal?

MS. WICHT: Your Honor, I'll object that Mr. Mone offered testimony in this case and his testimony in this case was that this was -- this graphic did not represent how Cardinal Health's system actually operated. So, I think this is mischaracterizing the record in the case.

THE COURT: Well, this is cross. I'm -- he's allowed some latitude here. I'm going to allow it.

Overruled.

Go ahead, Mr. Fuller.

MR. FULLER: Thank you, Your Honor.

BY MR. FULLER:

Q. Do you know what the next step in the system was?

A. My understanding in the system was to evaluate the held order.

Q. Questionnaire, fax, and/or call, which was the due

diligence component, right?
A. I have not seen this document before, so if you're representing that that's the evaluation, I -- I -- I observed in the data that they flagged orders that exceeded the threshold. The terminology used in the system is they held those orders. They then evaluated those orders. Some of the orders were cut and reported to the DEA and, based on the contextual analysis, some of the orders were cleared.
Q. Great. Let's talk about the contextual analysis. Have you -- do you believe that you reviewed all the due diligence to determine whether they did an adequate contextual analysis to dispel the suspicion of the flagged orders?
A. That was not what I was asked to do. I did not review the entire set of due diligence that occurred. It is my understanding that that due diligence was not necessarily consistently maintained over the years. I wouldn't have expected it to have been. I was looking for indications of the process, not to validate that each step in the process in every occurrence took place.
Q. So, and maybe I can short circuit this. What I'm wanting to establish is that you're not here offering any opinions as to the adequacy of due diligence that may have been conducted or not conducted by Cardinal Health, correct?
A. I have, with the benefit of 20/20 hindsight conducted

certain contextual analyses that demonstrate that there are reasonable explanations to an overwhelming majority of the transactions flagged by Mr. McCann's model or method. I am not here to testify to the adequacy or effectiveness of any particular piece of due diligence. I have not reviewed all of the due diligence.

Q. Okay. So, if I can digest what you've said, you're not here to provide any opinions as to the adequacy of Cardinal's due diligence at the time. You're providing a hindsight review of the orders to give them some sort of context that may justify those orders and shipments?

A. I am not speaking to the overall adequacy of the Cardinal due diligence process. My opinion is that the plaintiff experts don't look at due diligence at all. They don't acknowledge contextual analysis. They didn't look at what was produced.

I have looked enough at what was produced to determine that they did have a process for looking at the contextual analysis in a realtime basis. I then applied some contextual analyses with the benefit of 20/20 hindsight to demonstrate that there were factors at play even many years later and still observable that provide context to the ordering process. I am not, and I agree, I am not testifying to the adequacy of Cardinal's overall due diligence or the adequacy of any particular step.

Q. Now, you say Mr. Rafalski nor Mr. McCann gave any context or reviewed any due diligence. Are you aware that all of centralized due diligence that we looked at a moment ago that Cardinal identified is all on Mr. Rafalski's reliance list or are you unaware of that fact?

A. I have read his report and his testimony and he offers no description of -- he looks at the list and just says that's not good enough. He doesn't provide any description of, on a step-by-step basis, what about the due diligence was or was not adequate. In my estimation, Mr. Rafalski just looked at it and sloughed it all off to the side.

Q. So, the contextual factors that you identified, you talked about some of them with counsel, right? Talked about controlled versus non-controlled?

A. Correct.

Q. And you also mentioned in your report the data going back to '96 was a contextual issue that you listed, correct?

A. That's a method issue. I would not --

Q. Okay. Fair enough. The hydration -- hydrocodone being rescheduled, you listed that as a contextual issue, right?

A. That is correct.

Q. The proximity to a hospital, I think you said anything within a quarter of a mile, that was another contextual issue that you listed, correct?

A. That is correct.

Q. 304(b) [sic] contracts?

A. 340(b).

Q. I'm sorry.

A. Yes.

Q. Zip code here or the area code here is 304. I apologize. I'm sorry.

A. Oh, okay. 340(b) is a drug pricing program that makes drugs available to socioeconomic disadvantaged groups at favorable pricing through hospitals. And so, similar to proximity to the hospital, contracting with a hospital for distribution or filling of 340(b) products is a unique and pertinent activity.

Q. Now, I think you conceded that there would be additional contextual factors to potentially consider, right? You weren't using your list as an exhaustive list?

A. I think you needed to be there at the time to have a complete view of the context of each order.

Q. Right. Or review what was going on at the time or what was actually done at the time, correct?

A. Related to each individual order.

Q. Yes, absolutely. So, sort of the due diligence contextual issues as they existed at the time, correct?

A. Related to each order, correct.

Q. And you didn't look for that in Cardinal's productions, did you? Did you search Cardinal's productions? They

produced millions of documents. You didn't search for that in their productions, did you?

A. I may have had -- I didn't do an exhaustive search for that.

Q. Did you ask counsel to provide that to you? Did you say, hey, I want to see all the due diligence that was done at the time on certain of these orders?

A. I asked for an inventory of the due diligence that existed in the production.

Q. And we can compare your reliance list with the document that was shown us to the discovery response to determine whether you were given those documents or not, right? Because you would have listed them in your reliance document if you had been provided them?

A. If I had relied on it.

MR. FULLER: May I approach the witness, Judge?

THE COURT: Yes.

BY MR. FULLER:

Q. I've just handed you a Congressional Hearing Report entitled OxyContin Use and Abuse. It's Plaintiffs 41774. Have you seen this document before, Mr. MacDonald?

A. I may have. I don't recall. I've seen lots of government documents in this case. I don't recall if I've seen this one or not.

Q. And what's going in the country and things impacting

opioids or opioid abuse is another contextual factor to be considered, correct?

A. It's what's going on on a national basis when you're evaluating --

Q. National --

COURT REPORTER: I'm sorry --

MR. FULLER: I'm sorry.

THE WITNESS: What's going on on a national basis as you're -- and is known and well talked about when you're evaluating individual orders and you're being directed by the DEA that the vast majority of physicians are doing right by their patients and the DEA expected for distributions to happen, I don't know that looking at national trends was a required step in looking at the contextual factors around a particular order. This is the context of standard of care and opioid prescribing patterns on a national basis.

Q. Sure. So, let's look at what Congress was looking at back at the OxyContin Use and Abuse. If you turn to Page 10 --

A. Is it 10 as marked up top or in the Bates number?

Q. No. I think it's 6 marked up top.

A. Okay.

Q. If you go to --

A. I'm with you.

Q. -- bottom of that page, it says the last full sentence

on that page, while OxyContin diversion and abuse appears to have begun in rural areas, such as Appalachia, it now has spread to urban areas.

Do you see that?

A. I see that sentence, yes.

Q. And this was a congressional hearing related to the use and abuse of OxyContin. Is this something that could have been considered as a contextual factor?

MS. WICHT: Objection, Your Honor. I believe the witness has testified that he's not sure if he's ever seen this document before. So, I don't -- I'm not -- I object to him being asked to comment on it and how it would factor into contextual analysis.

THE COURT: Well, overruled. I think this is appropriate cross examination.

Go ahead, Mr. Fuller.

MR. FULLER: Thank you, Judge.

THE WITNESS: I cannot contemplate or I cannot come up with a way or a reason that when evaluating individual orders to pharmacies how this observation relates to individual orders. The distributors had to look at individual orders in the context of those orders and make a determination of whether or not they were of unusual size, pattern or frequency.

This is speaking to a national trend that was in the

public purview. It was in the purview of the DEA and, as you point out, Congress, and the medical community. I don't know how I would have applied that statement to evaluating one order from the next.

BY MR. FULLER:

Q. Even if you can't apply it to one order or the next, is it something to be considered generally?

A. My understanding is that the DEA requirements and what the DEA required of the distributors was to design systems to evaluate orders of unusual size, pattern or frequency. So, considered by who? I don't know who I would have -- it's not my role to say who should have been considering it, but I don't find relevance in that statement in the context of evaluating individual orders.

Q. Fair enough.

MR. FULLER: Judge, I would move in Plaintiffs' 41774 as a self-authenticating document for the purposes of notice only.

MS. WICHT: Your Honor, we object. I don't -- I don't think that this witness is a proper witness to move in documents. I don't think that -- with Mr. Fuller's moving it in for notice, I don't know notice to who. He's not established anything about anyone having this information. So, we would object to the admission of this document at this time.

THE COURT: How do I get around the hearsay on this?

MR. FULLER: Judge, I'm offering it for notice only. It's notice to the entire country.

THE COURT: Notice of what, Mr. Fuller?

MR. FULLER: OxyContin use and abuse, Judge. It's an investigation into the use and abuse of OxyContin. And now that Mr. Ackerman is standing up, I'll let him chime in.

MR. ACKERMAN: Judge, to the extent --

THE COURT: Welcome back, Mr. Ackerman.

MR. ACKERMAN: Well, thank you, Your Honor.

To the extent you are concerned about hearsay, I would note that the statement from the DEA that was read into the record would be a public record pursuant to Rule 803(8)(a).

THE COURT: Well, this is a congressional hearing and way back, days ago, we had the same issue come up and I didn't let the document in because of concerns I expressed about how objective these things are in the political context.

Ms. Wicht, do you want to say something else?

MS. WICHT: No. Well, no, Your Honor. I think we agree with, I guess, what I'm inferring as the path that the Court is on. The document is hearsay. There's not been -- there's not been any foundation laid as far as who it might be notice to.

THE COURT: I'm not going to admit the document, Mr. Fuller, but I think it's permissible for you to use as a basis for your cross examination.

MR. FULLER: Thank you, Judge.

THE COURT: So, you can use it to that extent, but I'm not going to admit it into evidence.

MR. FULLER: Thank you, Your Honor.

I'm going to move now and approach the witness, if I may, Judge?

THE COURT: Yes, you may.

MR. FULLER: MC-WV-01764.

BY MR. FULLER:

Q. Mr. MacDonald, this is a document that's already in evidence. I'm going to ask you a similar question here, if you don't mind. If you would turn to Page 14.

A. Was I supposed to get two copies?

Q. Oh, I'm sorry.

A. I missed what page you said to turn to.

Q. 14.

A. Again, per the Bates number or the page number?

Q. Per the created P stamp number, yeah. Bottom right. Bottom -- yeah, bottom right. It's the paragraph that starts with media reports. Do you see that?

A. I do.

Q. The second sentence in there reads, rural communities

in Maine, Kentucky, Ohio, Pennsylvania, Virginia and West Virginia were reportedly being devastated by the abuse and diversion of OxyContin.

Is that a factor that should be considered when distributing orders into West Virginia on behalf of the distributors?

A. My observation is that they are distributing orders to pharmacies in the context of an overall level of permissible distributions as published by the DEA in the aggregate production quota number. These numbers -- my observation is that they line up well with the prescribing. Well, particularly when you look at -- I've looked at this jurisdiction in the State of West Virginia, that the orders that were being distributed were in line with the volume that was being prescribed by the physicians within West Virginia. I don't know how I would use this statement to evaluate a particular order.

Q. Sure. And let's talk about the other contextual factors that you identified. You don't give any weight to them, correct? So, for example -- and let me try to clear that up.

When you say we look at a contextual factor of controlled versus non-controlled, you're not saying that just because it's a certain percentage that it means it's an okay order to ship, are you?

A. I am not trying to reach an independent conclusion of which orders were okay to ship or not to ship. My opinion is that Mr. McCann -- or Dr. McCann and Mr. Rafalski have not done anything to design an effective flagging or evaluation methodology themselves.

My opinion is that Cardinal had a system in place. It was threshold based. A threshold based system is appropriate. It is -- it's the beginnings of an algorithmic approach for identifying potential outliers. And I see indications that they were employing contextual analysis in the forms of their due diligence.

I independently throw out some examples of contextual analysis that Mr. McCann and Mr. Rafalski do not do. You're correct I don't weight one as being more important than the other, not to say that if I were there at that point in time, that Cardinal may have applied a relative waiting approach. I have not attempted to do so.

MR. FULLER: So, let's go to Demonstrative number -- Slide number 5, Gina.

BY MR. FULLER:

Q. Did you consider at all when you were looking at it -- or let me ask differently.

Would the contextual factor include the amount of opioids being shipped into differing states? Would that be a comparison that could be done?

A. There are -- again, macrolevel trends like this do not bear on the particular distinction between individual orders. This would not give me the ability to evaluate individual orders.

Q. Sure. But it could signal a red flag that might be -- should be looked into by one of the distributors, correct?

MS. WICHT: Your Honor, I'm going to object at this point as beyond the scope. The witness is here to testify about data and his analysis of data and what it showed and I think we've gone pretty far down the road on questions about, you know, things that should or shouldn't have been considered and things that may be red flags and I think we -- we've gone well beyond the scope of direct at this point.

THE COURT: Well, I'm going to allow this. He talked about the comparison of West Virginia pills and national averages and so forth and I think this is arguably relevant to that.

So, go ahead, Mr. Fuller.

MR. FULLER: Thank you, Judge.

BY MR. FULLER:

Q. So, here we're comparing West Virginia and the number of oxycodone pills that Cardinal shipped into West Virginia over the ARCOS time frame. And you remember what that was, right, Mr. MacDonald?

A. I do.

Q. 6 to 14?

A. Correct.

Q. Okay. And 131 million pills shipped into West Virginia; while Illinois, a state with a population of 12.8 million people, got 77.9 million dosage units. That's significantly different than the percentage of additional prescriptions that you were showing on a national basis for West Virginia, correct?

A. The -- this is isolated on Cardinal. The market share of each distributor by state is different. Certainly, distributors are stronger in certain states. You have significant practice patterns or standard of care differences from state to state.

My analysis demonstrates that the overall distributions of controlled substances in the state aligns with the rate above average of all pharmaceutical products into West Virginia. So, there are health and demographic differences from state to state.

I don't take any per se takeaways from this other than you've shown me two numbers and pointed that one number is larger than the other. That does not provide context to me.

I've demonstrated that the per capita distributions into West Virginia are below what the -- on a per capita basis what the DEA was publishing as an aggregate production

quota. They are in line with the prescriber level data, the rate at which West Virginia physicians were writing prescriptions. The distributions and the number of prescriptions are reasonably well aligned.

So, as a distributor evaluating individual orders, I don't know that there's anything they could have done with this data beyond what I've just described, looking at the APQ, et cetera, and it would not have allowed -- this data does not have a bearing on individual orders. Is that order of unusual size, pattern or frequency.

Q. Did you -- you listed it on your reliance material. Did you read Mr. Reardon's deposition?

A. I -- I don't recall all of the elements of it but, yes, I have read it.

Q. He was in charge of the anti-diversion program from basically the beginning of time until 2008; do you recall that?

A. I recall that he had a senior position, yes.

Q. Do you recall that he testified that this is the type of information that he would like to have been made aware of?

MR. WICHT: Objection, Your Honor. I don't know that that's in the record in this case and I don't know what the basis is for that question. I object.

THE COURT: I'm going to allow it. You're

entitled to a wide latitude here and this is arguably relevant.

Go ahead, Mr. Fuller.

THE WITNESS: I don't have his testimony memorized. I don't know that he said that or not.

BY MR. FULLER:

Q. So, let's go to Slide number 9. This compares West Virginia to Texas. Do you know Texas has 29.2 million people?

A. I -- I don't have state-by-state populations memorized, but that number seems plausible to me.

Q. We can agree it's a big state, right?

A. We can agree it's a big state.

Q. Okay. And they, as far as the oxycodone, while West Virginia got 131 million, Texas only got 79 million, almost -- a little more than half for a state that is about fourteen times the size of West Virginia. Would that be a contextual factor that you might want to consider?

A. Not necessarily. When I'm evaluating individual orders, it does not take into account Cardinal's market share between the two states. It does not take into account standard of care practices by the medical community. It does not have a bearing on individual orders.

Q. So, let's go to Demonstrative Slide 14. And these are the methodologies. The judge saw this yesterday with

another witness.

Do you recognize those as the methodologies A through F?

And it should be on the screen next to you, too, I think.

A. Those appear to be the six methodologies laid out by Mr. Rafalski and Mr. McCann.

Q. And each methodology is slightly different, correct, in how it's ran or how it operates?

A. They are not identical. They have similarities in that they're indiscriminate, but they have differences, as well.

Q. So, each of them, when they are ran, and I think you described the maximum monthly trailing six-month threshold, A, earlier. And the way it was done, or asked to be done by Mr. Rafalski, is to look at a six-month time frame and flag anything above the highest one of the past six months, right?

A. It looks at the seventh month in the context of the prior six months, that is correct.

Q. Right. And you said that methodology flagged a huge number of orders, correct?

A. A huge number of any numerical sequence that I put through it.

Q. But it's not that part of the methodology that flags so many of the orders, is it? The additional assumption that

Mr. Rafalski came up with related to the due diligence, or the lack thereof, is what caused the high volume of flagging; isn't that true?

A. A -- it is indiscriminate even in its ability. It does not identify outliers. The -- when you throw a sequence of numbers, where every number in the sequence is an expected number, like a random dice throw, it still identifies a meaningful percentage.

The percentages reported by Mr. McCann and Mr. Rafalski as flagged, a large portion of those percentages are flagged due to what they refer to as the carry-forward flagging methodology.

Q. And that's -- that carry-forward that you're referring to is the assumption that Mr. Rafalski has testified to because of the lack of due diligence, at least in his opinion, correct?

A. It's -- what it is related to, Mr. Rafalski -- I -- his opinions are his opinions. I view what he did as he didn't look at the due diligence.

He makes a blanket statement that whatever due diligence is observable, it's not good enough. He doesn't find a single element of due diligence, a site visit, a single site visit, that happened the month after a flagging event happened and say, well, yes, that -- that flag should now be turned off because some due diligence took place.

He makes no attempt to lay on top of and say what impact did the due diligence that they did do have on the flagging methodology. He ignores all of it.

Q. And so, that's my question. But we established earlier, right, that you're not here to evaluate the due diligence, so you can't say whether any due diligence was good or not, correct, that Cardinal did?

A. I cannot speak to the overall adequacy of Cardinal's due diligence. It's not what I was asked to look at.

I can point to the fact that they did some due diligence and Mr. Rafalski did not consider that due diligence on a case-by-case basis, yet, he carries forward the flagging on a case-by-base basis.

Q. And you would agree that all of these differing contextual factors should be considered, whether by Mr. Rafalski and Mr. McCann, Dr. McCann, or Cardinal at the time, correct?

A. I have stated that it is important to conduct contextual analyses. I am not prescribing a required list of contextual analyses. I have simply presented some examples of the types of contextual analyses I would have been looking at as I sat there.

Some of these are contextual analyses I know Cardinal was looking at. They did look at the controlled percentage, for example. It's contained in the due diligence files.

Q. And you didn't devise a system to flag orders yourself, did you?

A. I did not independently design a flagging methodology, no. I was not asked to do that.

MR. FULLER: Let's go, if we have it, to Defendant's Demonstrative Slide number 7.

BY MR. FULLER:

Q. And in keeping my promise both, actually, to the Court and Ms. Wicht, I'm almost done with you, okay?

A. Okay.

Q. All right. So, this is a slide you testified to about earlier, right?

A. This is the slide, yes.

Q. And if we're looking at it -- and I think it will still write. Total controlled substances is almost 15 percent, right?

A. It's just under 15 percent, yes.

Q. Half nearly is opioids, correct?

A. Your math is reasonable, yes.

Q. Thank you. You're probably the only one that thinks so.

Are you aware that that's a contextual factor that should be considered, that half of the controlled substances that Cardinal was shipping in to CT2 was opioids?

A. That is not outside of the norm of what I've observed

in several jurisdictions or regions around the country.
Q. Where do you believe that you have also seen that half of the controlled substances were opioids?
A. In national data within -- well, let me put it this way. Data that has been produced in other litigations.
MR. FULLER: Judge, if I can have one minute?
(Pause)
MR. FULLER: Ms. Gina, if we can go back to Slide number 14 from our slide deck.
BY MR. FULLER:
Q. So, are you aware that Cardinal used a -- in setting thresholds, used a three-times multiplier for the average?
A. It's my understanding that they applied it in a different fashion and that the Rafalski/McCann application is not identical to what -- between what Cardinal did in the early years on a limited geographic basis.
Q. Is that because of the assumption that they used or there were other differences?
A. I don't know what you're referring to.
Q. The assumption once it's flagged, it's always flagged or the lack of due diligence. Is that the difference you're making or is there some other difference?
A. My understanding is that the application of it is also different. I don't recall the precise nature of the difference.

Q. Okay. Now, you're aware that the country's in an opioid epidemic, right, and that epidemic has been going on for sometime?

A. I understand that there have been negative impacts of opioid use in the U. S. I understand that there's a pain crisis, as well. But, yes, I'm aware that there are downsides to the use of opioids.

Q. And if you're setting something that's three times the average, whatever you're using as your average will dictate how high that is, correct?

MS. WICHT: Objection, Your Honor. Mr. MacDonald previously testified that he hadn't evaluated how thresholds were set and he was not here to offer any opinions on how they should be set.

THE COURT: Well, overruled. Mr. Fuller, you can ask him. Let's --

MR. FULLER: Let me see if I can clean it up a little bit.

BY MR. FULLER:

Q. If the country is in the middle of an opioid epidemic, should that be considered when setting thresholds or not in your mind?

A. In setting thresholds for identifying orders of unusual size, pattern or frequency, Cardinal employed a method for setting thresholds. This particular threshold that you're

reporting -- responding to is indiscriminate based on the particulars of a pharmacy. That sets the same threshold for all pharmacies, whether or not it's the CVS in a particular market, or a particular -- a small pharmacy on the outskirts of town.

Q. And last thing, Mr. MacDonald, I want to clarify. Earlier you testified that you saw the Cardinal transactional data from '96 to 2018, correct?

A. That is correct.

Q. But just a moment ago you testified about a more limited set of data or limited time frame. I want to say you said 2013. Are you related to -- or relating that to the due diligence that you reviewed?

A. The thresholds dataset where the thresholds are maintained in electronic format.

Q. Yes, sir.

A. The data produces from 2013 forward. The 1996 data forward is the actual order data, the transactional data.

Q. So, you don't recollect seeing threshold data prior to 2013?

A. Not in a comprehensive electronic fashion, no.

Q. All right. Did you apply Cardinal's system to the data, to their own data?

A. The threshold system, I applied the thresholds contained in electronic format to the Cardinal data, yes.

Q. For the 2013 forward?

A. That's when those thresholds were in place. The thresholds are dynamic. They evolve over time as the pharmacies evolve over time.

MR. FULLER: Judge, I don't have anything further.

THE COURT: Anything else, Ms. Wicht?

MS. WICHT: At the risk of trying the Court's patience, I have, I think, five questions.

THE COURT: Okay. Go ahead, please.

MS. WICHT: Thank you.

RE-DIRECT EXAMINATION

BY MS. WICHT:

Q. Mr. MacDonald, you were asked some questions about due diligence files by Mr. Fuller and I just have a few follow-up questions on what it is that you reviewed. Did you review data reflecting thresholds that had been set by Cardinal Health with respect to its pharmacy customers in Cabell-Huntington?

A. I have.

Q. Did you review data reflecting orders that were held as a result -- by Cardinal Health as a result of the application of those thresholds?

A. I have.

Q. Did you review data reflecting the results of the analysis of held orders?

A. Not the analysis itself in a comprehensive basis, but as you point out, the result was the order cut and reported or was it subsequently shipped, yes, I did review the results.

Q. Did you review data reflecting the occurrence of site visits?

A. I did.

Q. Again, not analyzing the adequacy of the visits themselves, but data reflecting that they occurred?

A. I have.

Q. And are you aware that those datasets that you just described reside outside of Cardinal Health's centralized due diligence files?

A. I -- I am aware of that, yes.

MS. WICHT: Thank you very much. That's all I have, Your Honor.

THE COURT: Do you have anything else, Mr. Fuller?

MR. FULLER: No, Your Honor.

THE COURT: May Mr. MacDonald be excused?

MR. FULLER: Unless he wants to hang out for the weekend, Judge.

THE WITNESS: Better than Virginia. I'll stay in West Virginia.

THE COURT: You can stay all day, Mr. MacDonald.

(Laughter)

MR. FULLER: Good save.

THE COURT: You're excused, Mr. MacDonald.

THE WITNESS: Do I do anything with the exhibits?

THE COURT: You can just leave them there and we'll take care of them.

THE WITNESS: Thank you very much.

THE COURT: Okay. Is there anything else we need to do before we leave for the weekend, Mr. --

MR. FARRELL: Oh, yes. The defense has identified six witnesses that they intend to call next week. And so would that -- more than six?

MS. MAINIGI: It's the list that was provided.

MR. FARRELL: And so, does that mean -- we would like to have some clarification whether or not the remainder of the subpoenaed witnesses that are not on that list may be officially released.

MS. MAINIGI: Your Honor, we have certainly provided notice to Mr. Farrell for Monday. I'm happy -- we're happy to talk to him offline and give him direction on any witnesses he has questions about.

THE COURT: Who has the witnesses subpoenaed, Mr. Farrell?

MR. FARRELL: I'm sorry? Say again.

THE COURT: Do the defendants have witnesses subpoenaed?

MR. FARRELL: Yes, Your Honor.

THE COURT: Well, as long as they give you a list of the ones they expect to call, isn't that good enough?

MR. FARRELL: If you say so. We have a number of -- we have a number of people around the state who have been subpoenaed and they're holding calendars and physicians that are holding calendars. And so, I'm simply asking for the Court to declare that --

THE COURT: Subpoenaed by the defendants, right?

MR. FARRELL: Yes, Your Honor.

THE COURT: Well, why don't you talk about this and if you can let any of them go, I encourage you to do that.

MS. MAINIGI: Absolutely, Your Honor. This is the first that it's being raised. It was not raised with us previously, but we're happy to do that right now after court is dismissed.

THE COURT: All right.

Is that good enough, Mr. Farrell?

MR. FARRELL: I doubt it, but we'll talk about it again on Monday.

THE COURT: Well, that's the best you're going to get right now.

MR. FARRELL: Yes, sir.

THE COURT: All right. But you have the list for

next week, right?

MS. MAINIGI: Yes, Your Honor.

MR. FARRELL: Yes.

THE COURT: Are we still going to finish next week?

MS. MAINIGI: That's our strong expectation, Your Honor.

MR. NICHOLAS: Yes, we will finish next week.

MR. HESTER: That's what we're planning, Your Honor.

THE COURT: Well, good, as I said yesterday. If there's nothing else, I will see everybody Monday morning at 9:00.

MS. MAINIGI: Thank you, Your Honor. Have a good weekend.

(Trial recessed at 3:46 p.m.)

CERTIFICATION:

I, Ayme A. Cochran, Official Court Reporter, and I, Lisa A. Cook, Official Court Reporter, certify that the foregoing is a correct transcript from the record of proceedings in the matter of The City of Huntington, et al., Plaintiffs vs. AmerisourceBergen

Drug Corporation, et al., Defendants, Civil Action No. 3:17-cv-01362 and Civil Action No. 3:17-cv-01665, as reported on July 9, 2021.

S\Ayme A. Cochran
Reporter

s\Lisa A. Cook
Reporter

July 9, 2021
Date

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